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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,970	01/03/2001	Hideaki Nomura	081356/0156	8299

7590 04/10/2002  
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Washington Harbour  
Suite 500  
3000 K Street NW  
Washington, DC 20007-5109

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/10/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/720,970

Applicant(s)

NOMURA ET AL.

Examiner

Sharmila S. Gollamudi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

Claims 1-7 and 9-12 are included in the prosecution of this application.

Election of proteins on March 27, 2002 is acknowledged.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 2, 6, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/24149.**

WO 93/24149 discloses a powder composition containing HPMC, chitosan, and a medicament (Note example 1). The reference teaches the composition for the application to the nasal mucosa (pg. 1, paragraph 1).

**Claims 1, 7, 9, 10, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 07-118170.**

JP 07-118170 discloses a powdery composition for nasal administration containing chitosan and an active peptide (Note abstract).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/24149 or JP 07-118170 cited above, in view of JP 10-095738.**

As set forth above, WO 93/24149 and JP 07-118170 teach a mucosal composition containing a medicament and cationic polymer.

WO 93/24149 and JP 07-118170 do not teach polyarginine in the composition.

JP 10-095738 teaches a transmucosal preparation containing a medicament and poly-L-arginine. The arginine compound raises the permeation rate of the medicament transmucosally, increasing its therapeutic effect. (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made, to combine the references since all the references teach the same field of endeavor and teach method of improving transmucosal absorption of a medicament. One would be motivated to use polyarginine in a mucosal composition, such as WO 93/24149 or JP 10-095738, to improve the absorption of the medicament thorough the mucosa, therefore increasing its therapeutic effect as taught by JP 10-095738.

**Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/24149 or JP 07-118170 cited above, in view of JP 4026617.**

As set forth above, WO 93/24149 and JP 07-118170 teach a mucosal composition containing a medicament and cationic polymer. The WO reference teaches chitosan, a cationic polymer, provides high availability of the active ingredient (pg. 1,

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paragraph 1). The JP reference teaches the cationic polymer as a suitable carrier for an active peptide for nasal administration (Note abstract).

The references do not teach the instant cationic polymer (AEA).

JP 4026617 teaches agent matrix containing an active agent and AEA for nasal mucosa.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references since all the references teach a mucosal composition containing an active agent and cationic polymer. One would be motivated to use JP 4026617's cationic polymer AEA with a reasonable expectation of obtaining similar results since WO 93/24149 and JP 07-118170 both teach cationic polymers and active agent composition for mucosa.

**Claims 1-7 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 90/09780.**

WO 90/09780 discloses an active agent such as insulin and a polycationic substance for administration to the mucosa (Note abstract and example 5). The reference teaches the use of polycationic substances improve the formulation since it eliminates the need for additional enhancers (pg. 3, second paragraph). The polycationic substances that are suitable are polyaminoacids, co-polymethacrylates, etc. (pg. 5). The composition is taught in a powder or microsphere form (pg. 3, last paragraph). The reference teaches a gelling agent for increased viscosity to retain the formulation on the mucosa (pg. 6, paragraph 2). Further, prior art in which a high

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molecular drug and a gelling agent (hydroxyethyl cellulose) are administered nasally is disclosed (pg. 2, second paragraph).

WO 90/09780 does not specify the preparation in powder form in the examples or exemplify the instant cationic polymers.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the suitable cationic polymers taught by WO 90/09780 with the reasonable expectation of similar results since the reference teaches the use of polycationic substances, in general, improve the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a drug suitable for the intended treatment since the WO reference teaches the use of various drugs for the composition.

### **Correspondence**

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

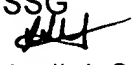
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

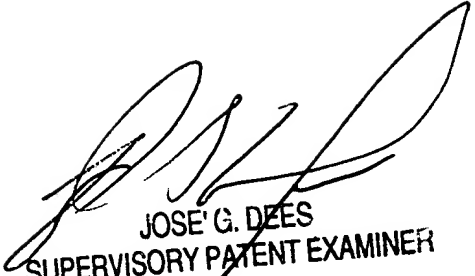
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SSG

  
April 4, 2002

  
JOSE G. DEES  
SUPERVISORY PATENT EXAMINER

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